

Calcium requirements of pregnant women in The Gambia

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| Submission date 11/09/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 06/11/2007 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 11/06/2024 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Calcium requirements of pregnant women in The Gambia

Study objectives
Calcium intakes of pregnant women in rural areas of The Gambia are considerably below recommended levels. There is evidence to suggest that low calcium intakes during pregnancy

may be associated with an increased incidence of pregnancy-induced hypertension, reduced maternal bone mineral content, low breast-milk calcium concentrations post-partum, and sub-optimal bone development and growth of the child. The aim of this study is to determine whether pregnant Gambian women would benefit from an increase in calcium intake.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Medical Research Council (MRC)/Gambian Government Joint Ethics Committee (ref: SCC/EC 585/559).

Study design

Randomised double blind placebo controlled trial

Primary study design

Intentional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Calcium deficiency in pregnancy

Interventions

1500 mg Calcium (Ca) orally per day or placebo until delivery.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Calcium

Primary outcome(s)

1. Maternal blood pressure at 36 - 38 weeks gestation
2. Breast-milk calcium concentration during lactation
3. Post-partum bone mineral content of mother and baby

Key secondary outcome(s)

1. Infant growth and development:
 - 1.1. Weight, measured within 24 hours of birth and at 2, 13 and 52 weeks
 - 1.2. Crown-heel length, measured within 5 days from birth and at 2, 13 and 52 weeks
 - 1.3. Head circumference measured within 5 days from birth and at 2, 13 and 52 weeks
2. Infant blood pressure and growth, measured every two years from age 3
3. Maternal post-partum blood pressure, measured at 2, 13 and 52 weeks post-partum

Completion date

31/12/2000

Eligibility

Key inclusion criteria

Consenting pregnant women at booking.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

No specific exclusion criteria at booking.

Date of first enrolment

01/01/1995

Date of final enrolment

31/12/2000

Locations

Countries of recruitment

United Kingdom

England

Gambia

Study participating centre

MRC Human Nutrition Research

Cambridge

United Kingdom

CB1 9NL

Sponsor information

Organisation

Medical Research Council (UK)

ROR

<https://ror.org/03x94j517>

Funder(s)

Funder type

Government

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|-------------------------|--------------|------------|----------------|-----------------|
| Results article | results | 01/03/2006 | | Yes | No |
| Results article | results | 01/08/2010 | | Yes | No |
| Results article | results | 01/12/2011 | | Yes | No |
| Results article | follow-up study results | 01/09/2013 | | Yes | No |
| Results article | results | 01/10/2013 | | Yes | No |

[Results article](#) follow-up on blood pressure and growth 18/04/2024 11/06/2024 Yes No